K010137

FEB 1 3 2001

510(k) Summary
For
Orbiter II CCI/SPECT

Special 510(k) – Orbiter II CCI / Spect

Device Name

The device trade names and common classification names are:

Proprietary Name: ORBITOR II CCI / Spect
[Camera Controlled Interface]

Common Name: Gamma Camera

Address and Registration No.

The address and registration number of the manufacturing site is:

FDA Registration Number: 1419826

Siemens Medical Systems, Inc.
Nuclear Medicine Group
2501 North Barrington Road
Hoffman Estates, IL 60195-5203

Tel: 847-304-7700
Fax: 847-304-7701

Device Class

Gamma Cameras have been classified as Device Class II 901YX.

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for Gamma Cameras.

Predicate Device Information

The predicate devices are:

ORBITER II	Counter Balance Camera,	[K850397 - 26 Mar 1985]
ICON	Computer System,	[K914350 - 22 Nov 1991]

Labeling and Intended Use

Labeling and Draft Instructions for Use can be found in **Attachment 1.**

The changes to the instructions reflect the addition of the hardware/software interface. Otherwise, the ORBITER II is identical to

Intended Use

The ORBITER II / CCI system is adaptable for :

- Clinical Imaging
- Circular orbit emissions computed tomography
- Non-circular orbit emissions computed tomography

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- Whole Body scanning

This is the same intended use as previously cleared for the ORBITER II Counter Balance Camera K850397.

Orbiter II / CCI is a Gamma Camera system for nuclear medicine used to perform static, gated and dynamic studies, as well as spect procedures, on standing, seated or recumbent patients.

The Indications for Use statement can be found in **Attachment 2.**

Device Description And Comparison

The device description of the ORBITER II CCI is identical to the combining of each of the following systems:

ORBITER II	Counter Balance Camera,	[K850397 - 26 Mar 1985]
ICON	Computer System,	[K914350 - 22 Nov 1991]

The ORBITER II CCI is a gamma camera system, accommodating both the ZLC 370 and the ZLC 750 Digitrac detectors. It has a counterweight mounted on a column-type pedestal. Two separate electromechanical drives independently generate radial and orbital motion of the detector head

The ICON Computer System is a nuclear medicine acquisition workstation dedicated to controlling and framing data from analog output gamma cameras.

The only modifications that were made are:

The addition of a hardware /software interface between the ORBITER II and the ICON Computer System. This interface permits communication of data between the two devices.

Substantial Equivalence

The modified ORBITER II / ICON CCI system have the following similarities to those separate products which previously received 510(k) concurrence:

- have the same indicated use,
- use the same operating principle,
- incorporate the same basic product design
- incorporate the same materials,
- have the same shelf life.

A comparison of functions is provided in **Attachment 7.**

Substantial Equivalence (cont'd)

In summary, the ORBITER II / ICON CCI Gamma Camera described in this submission are, in our opinion, substantially equivalent to the two predicate devices.

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Summary of Design Control Activities	The risk analysis method used to assess the impact of the modifications was based on a Failure Modes and Effects Analysis (FMEA). This analysis built upon the previous risk analysis and incorporated the interface between the ORBITER II and the ICON system. The FMEA analysis is included in **Attachment 6.** The design verification tests that were performed as a result of this risk analysis were identical to the testing for the individual systems. The individual components were tested, assembled with the interface, and the exact tests were run again to demonstrate no change in performance or safety levels.
510(k) Statement	A 510(k) Statement for the ORBITER II / ICON CCI is included in **Attachment 4.**
Truthful and Accuracy Certification	A certification of the truthfulness and accuracy of described in this submission is provided in **Attachment 5.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 3 2001

Mr. Ronald Nolte
Director of Regulatory Affairs and Quality Assurance
Siemens Medical Systems, Inc.
Nuclear Medicine Group
2501 North Barrington Road
HOFFMAN ESTATES IL 60195-5203

Re: K010137
ORBITER II Counter Balance Camera CCI
Dated: January 9, 2001
Received: January 17, 2001
Regulatory Class: II
21 CFR §892.1200/Procode: 90 KPS

Dear Mr. Nolte:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number: K010137

Device Name: Orbiter II CCI / SPECT

Indications For Use:

Orbiter CCI / SPECT is a gamma camera system for nuclear medicine, used to perform static, gated, and dynamic studies, as well as spect procedures, on standing, seated or recumbent patients.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

David A. Legrow

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010137